

REMARKS

Claims 1-3, 5-20, 31 and 32 are currently pending in the application.

Rejections Based on Pietsch, et al.

In the interest of brevity, Applicants incorporate by reference all previous arguments concerning Pietsch, et al., and, in particular the arguments set forth in the Response mailed November 26, 2003 and the Response mailed January 21, 2004, as if fully stated herein, and maintain that Pietsch, et al. has been improperly applied.

Section 102 Rejection

In paragraph 2 on page 2 of the Office Action, claims 1-8, 10-19, and 31 are rejected under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al. (U.S. Patent No. 4,778,461). Applicants respectfully traverse the rejection.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Furthermore, all of the elements must be arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984). Applicants respectfully submit that Pietsch, et al. do not teach every element of Applicants' invention set forth in independent claims 1 and 10, and therefore fails to anticipate claims 1 and 10.

Applicants respectfully submit that the Office Action does not make out a prima facie case of anticipation for the following reasons.

Pietsch et al. do not teach each and every claim element set forth in independent claims 1 and 10. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. Denied, 500 US 904 (1991). Pietsch et al. do not teach the identical invention in as complete detail as is contained in independent claims 1 and 10. "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP Section 2131.

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Conell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

The invention set forth in claim 1 is a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device. The polymer itself, and not the substrate, provides the form of the device. Pietsch et al. fail to disclose this feature, and fail to disclose each and every element of the invention set forth in claim 1.

Further, Applicants maintain that Pietsch must be considered for its antithetical teachings. As stated in col. 1, lines 63-65, and col. 3, lines 58-62, "support ring...

preferably consists of a plastic material," and that polyamides with short glass fibers are particularly suitable and preferred. Pietsch et al refer at col. 5, lines 31-32 to "production of the support ring by injection molding." Further, Pietsch et al clearly state at col. 5, lines 49-50, "As already described, the support ring should preferably consist of thermoplastics." Thus, Pietsch, et al. teach away from providing a support ring made of an inorganic material. In view of the teachings of Pietsch, et al., one skilled in the art would be taught or motivated to provide a support ring of a plastic material, and would not be taught to provide an inorganic substrate as set forth in claim 1.

With regard to claim 10, the Examiner maintains, "Since Pietsch et al. teaches that the crosslinked silicone rubber (polydimethylsiloxane) has high fatigue strength in alternate bending, a high breaking strength of at least 8N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400%, *in the absence of a showing to the contrary, the examiner has taken the position* that the composite can be bent by at least 100 degrees while remaining elastic, by about 180 degrees without extending the component beyond its elastic limit, and by about 60 degrees for about 40 million cycles to about 400 million cycles without significant structural failure." Applicants cannot find a teaching of these features in Pietsch, et al. Without a reference describing the absent elements, the section 102 rejection cannot be maintained. In order to meet this element, it appears the Examiner is taking judicial notice or using personal knowledge. The Examiner is respectfully requested to either produce a reference specifically describing each and every element of the invention as claimed, or to submit an affidavit as required by 37 CFR Sec. 1.104(d)(2).

Pietsch et al. fail not only to teach each and every element of the invention as set forth in claims 1 and 10, but also fail to teach each and every element as arranged in the claims.

In view of the foregoing, Pietsch, et al. neither anticipate nor render obvious independent claims 1 and 10, either singly or in combination with other cited references.

Dependent claims 2-8 and 31, and claims dependent claims 11-19, which are dependent from independent claims 1 and 10, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over Pietsch et al. While Applicants do not acquiesce the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 10. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-8, 11-19, and 31 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-8, 10-19, and 31 under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al.

Section 103 Rejections

In paragraph 3 on page 2 of the Office Action, claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pietsch, et al. in view of Sumimoto Electric Co. (Abstract, JP 59192366). In paragraph 4 on page 2 of the Office Action, claims 9 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pietsch, et al. in view of MacGregor (U.S. Patent No. 4,627,836). Applicants respectfully traverse these rejections. Applicants refer the Examiner to the arguments stated hereinabove.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the cited combination of prior art fails to disclose all the claim limitations.

Applicants contend the stated rejections based on Pietsch, et al. cannot be maintained under the circumstances, as the present invention as claimed patentably distinguishes over Pietsch, et al., either singly or in combination with other cited references. The phrase "in the absence of a showing to the contrary....," is evidence of impermissible hindsight reconstruction in view of Applicants' disclosure. The Office Action fails to provide a specific reason why it would have been obvious to combine the references. A *prima facie* showing of obviousness has not been shown as to any section 103 rejection based on Pietsch, et al. (rejection of claim 20 in view of Pietsch et al. and Sumimoto Electric Co., and rejection of claims 9 and 32 in view of Pietsch et al and MacGregor).

Applicants respectfully request withdrawal of the rejection of claim 20 under 35 U.S.C. § 103(a) over Pietsch, et al. in view of Sumimoto Electric Co. Applicants further respectfully request withdrawal of the rejection of claims 9 and 32 under 35 U.S.C. § 103(a) over Pietsch, et al. in view of MacGregor.

Paragraphs 5-15

In response to Paragraphs 5-15, Applicants refer the Examiner to its arguments made November 26, 2003 and January 23, 2004, in addition to arguments hereinabove, though Applicants reserve the right to present additional arguments in support of patentability.

Applicants maintain that the invention set forth in claim 1, "a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device," patentably distinguishes over Pietsch et al. Further, Applicants maintain that the invention set forth in claim 10, "A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate, wherein the flexible composite component can be bent at least about 100 degrees without extending the flexible composite component beyond its elastic limit," patentably distinguishes over Pietsch et al.

In response to paragraph 15, to the extent the Examiner's contention is understood, Applicants disagree, and reiterates their previous statement that the composite in MacGregor is formed into the shape of the device, unlike the subject matter of claim 1, where the polymer alone provides the shape or form of the device. Thus, the composite in MacGregor is formed into the shape of the device, unlike the subject matter of claim 1, where the polymer alone provides the shape or form of the device.

Conclusion

In view of the reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims, i.e., claims 1-3, 5-20, 31 and 32.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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Date: July 1, 2004

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